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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,669	01/25/2002	Diane E. Goade	MC-158.USA	9994

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EXAMINER	
LUCAS, ZACHARIAH	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,669	GOADE ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *2,3,14,16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-13 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Currently, claims 1-17 are pending in the application. In the prior action, mailed on March 23, 2004, claims 1, 4-13, and 15 were rejected, and claims 2, 3, 14, 16, and 17 were withdrawn as to non-elected inventions. In the Response of July 23, 2004, the Applicant amended claims 1, 4-10, 12, and 15.

2. Claims 1, 4-13, and 15 are under consideration.

Claim Objections

3. **(New Objection- Necessitated by Amendment)** Claim 1 is objected to because of the following informalities: in line 11 (part f)) of the claim, the claim refers to "untraviolet radiation." It appears that this should read - - ultraviolet radiation.- - Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **(Prior Rejection- Maintained)** Claims 1, 4-13, and 15 were rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is the step of correlating the reactivation with the effectiveness of the tested composition for the indicated

function (i.e., inhibition of reactivation or protection from UV). The amendments of claims 1 and 4 are noted. However, the amendments do not correlate the detection of reactivation to the effectiveness of the compound. It is suggested that language such as - -wherein a reduced or delayed reactivation indicates that the compound is effective to inhibit viral infection reactivation- -.

The rejection is also maintained with respect to claim 5 and its dependant claims for the reasons of record. It is suggested that a phrase such as - - wherein the absence of such reactivation indicates that the compound is an effective ultraviolet protectant- -.

6. **(New Rejection-Necessitated by Amendment)** Claims 1, 5-11, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is treated as representative. This claim has been amended to read on methods involving the use of one or more mice. However, in later steps, the claim refers only to the mouse (singular form). It is unclear if the single mouse is intended to be the same as the one or more mice. It is suggested that the claims be amended to refer either to - - said one or more mice- -, or to - - each mouse- - (as is done in claim 4), rather than referring to "the mouse." Clarification is required.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. **(New Rejection-Necessitated by Amendment)** Claims 1, 4, 5-13, and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection. There is no written description support for a genus of methods involving a "statistically relevant sample" of mice in the application. The amendments to the claims, inserting reference to such samples, therefore constitute New Matter to the application. Applicant is required to cancel the New Matter from the claims, or to point out where support for the rejected subject matter may be found in the application.

9. **(Prior Rejection- Withdrawn)** Claims 1, 4, and 6-13 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method to determine if a composition is effective to prevent HSV reactivation, does not reasonably provide enablement for a method to determine the ability of a composition to inhibit such reactivation. In view of the amendment of the claims, the rejection is withdrawn.

10. **(Prior Rejection- Withdrawn)** Claims 1, 4, 6, and 8-13 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method to determine if a composition is effective to prevent HSV reactivation wherein the radiation used to induce HSV reactivation is ultraviolet radiation, does not reasonably provide enablement for

methods where other forms of radiation are used. In view of the amendment of the claims, the rejection is withdrawn.

11. **(Prior Rejection- Maintained)** Claims 1, and 4-13, and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods wherein a statistically significant number of animals are infected and used, does not reasonably provide enablement for methods involving the use of a statistically insignificant number of animals (e.g. 1, or "two or more"). Applicant has amended the claims to require the obtaining of a "statistically relevant sample of one or more mice." However, the Applicant has not established that a single mouse would ever be statistically significant. In the specific case at hand, it is noted that whether a single mouse would be able to both host a primary infection and to be an effective host in reactivation studies is in each case unpredictable. Under such circumstances, even where those practicing the claimed methods are looking for a binary outcome (as suggested by application on page 7 of the Response) a single mouse would not be sufficient to provide a statistically significant result. In view of the uncertainty as to whether any particular mouse would be an effective model of infection reactivation, the Applicant has not provided an enabling disclosure for embodiments wherein the statistically significant number of mice is one.

12. **(Prior Rejection- Withdrawn)** Claims 1, and 4-13, and 15 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods wherein the animal is either a SKH-1 or B6129 mice, does not reasonably provide enablement for methods wherein any animal is used. The Applicant has amended the claims such that they are

limited to methods of using mice, and has provided arguments in support of the amended claims. The rejection is withdrawn in view of the amendments and arguments presented.

13. **(Prior Rejection- Maintained)** Claims 5, 6, 8, 10, 11, and 15 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims were rejected because the claims do not allow one of ordinary skill in the art to determine whether the composition has UV protection activity or an anti-viral activity. In the arguments in traversal, the Applicant argues that the claim is directed not to the determination as to whether a compound has ultraviolet protective activity, but as to how effective such an activity is in a compound already determined to have such a protective activity. The argument would be found persuasive except that the claims offer no means by which those in the art can determine how effective the compound is. A measurement to determine the relative efficacy of a compound would require that the methods of determining such efficacy involve a step of comparing the results of the test compound with those of some form of control (i.e. a basis against which the degree of effectiveness can be measured). There is no such step in the present claims. The rejection is therefore maintained.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. **(Prior Rejection- Maintained)** Claims 1, 4, and 6-13 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Norval (J Gen Virol 68:2693-98) in view of Wright (U.S. Patent 5,646,155), and further in view of Spruance et al. (Am J Med 85 (Supp 2A): 43-45) and Rooney et al. (J Infect Dis 166:500-06). The claims have been described above and in the prior action. The Applicant traverses the rejection on two grounds. First, the Applicant argues that the references teach away from the claimed invention in that Norval and Spruance indicate that the mice must be exposed to radiation prior to the test in order for the method to be effective, whereas the present claims are drawn to methods wherein the mice are exposed to UV radiation only after the initial infection by the virus. Second, the Applicant argues that the present claims are directed to methods wherein UV radiation is the only factor for inducing reactivation, whereas the art references teach the use of multiple factors.

The Applicant's first argument in traversal is that the teachings of Norval and Spruance supposedly teach away from the claimed methods. The Applicant argues that these references teach that "UV exposure prior to primary infection is necessary" to induce recrudescence. However, the citations made to the references do not make such a positive statement. Rather, the references suggest that such pre-infection UV exposure "affects the virus-host interaction and accounts for a high incidence of recrudescence." Norval, abstract. The reference therefore indicates that the pre-infection exposure results in a higher rate of recrudescence, but does not teach that such exposure is required. Spruance does not make any assertion of the necessity of

pre-infection UV exposure over the teachings of Norval. Thus, the teachings of these references do not, as the Applicant suggests, teach away from the claimed methods.

With reference to the second argument in traversal (the use of multiple factors for inducing reactivation in the art), the Applicant is here presenting an argument based on limitations that are not present in the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In the present case, the claims are drawn to methods "comprising" the exposure of the area of abrasion to UV radiation. It is noted that the claim indicates that the claims "comprise" such a step. The term "comprise" is open language, allowing for the presence of additional steps, and therefore additional factors, that are not specifically set forth in the claims. Thus, the claims read on methods wherein UV radiation is not the sole factor for inducing reactivation.

Further, even if the claims were so limited, the Norval reference nowhere teaches that both tape-stripping (or other non-UV factors) and UV must be used to induce recrudescence. To the contrary, the teachings on pages 2695-96 indicate that, while tape-stripping increased the incidence of reactivation, reactivation also occurred in mice not exposed pre-infection to UV that were not tape stripped as well as in mice that were tape-stripped. See, Table 1, page 2695. While the rate of reactivation in the mice not pre-exposed was less than that of the mice that were, the reference nonetheless indicates that exposure to UV prior to infection is not a requirement for infection reactivation.

The Applicant's arguments in traversal are therefore not found persuasive, and the rejection is maintained for the reasons above, and the reasons of record.

16. **(Prior Rejection- Maintained)** Claims 5 and 15 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Norval, Wright, Rooney, and Spruance as applied above, and further in view of the teachings of Rooney et al. (Rooney II, Lancet 338: 1419-22- of record in the March 2002 IDS). The Applicant traverses this rejection on the same grounds as presented above with respect to the rejection above. For the reasons above, and the reasons of record, the rejection is maintained.

Conclusion

17. No claims are allowed.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

James C. Housel
9/20/04

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